#### IN THE UNITED STATES DISTRICT COURT

#### FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LYNN STREET, :

Plaintiff, : CIVIL ACTION

:

V.

:

SUNBEAM PRODUCTS, INC.

CVS PHARMACY, and : NO. 07-2772

CVS/CAREMARK CORPORATION

:

Defendants.

#### **MEMORANDUM**

BUCKWALTER, S.J. November 13, 2008

Currently pending before the Court is a Motion for Summary Judgment by Defendants Sunbeam Products, Inc. ("Sunbeam") and CVS Caremark Corporation ("CVS") (collectively "Defendants"). For the reasons which follow, the Motion is denied.

#### I. FACTUAL AND PROCEDURAL HISTORY

The present lawsuit alleges strict liability, negligence and breach of warranty resulting from burn injuries sustained by Plaintiff Lynn Street on September 12, 2005, following her use of a hot pack (the "Hot Pack"), contained in the Sunbeam Products Chill It Hot N' Cold Pain Relief System, model 1749 (the "Pain Relief System"). The Hot Pack was manufactured by Cryopak, a Canadian entity, distributed by Sunbeam, and sold to Plaintiff by CVS. Cryopak is not a party to this action.

#### A. The Events Surrounding the Injury

At the time relevant to this lawsuit, Plaintiff was a fifty-three year old woman with

diabetes, who had previously undergone multiple medical procedures in and around her abdominal region, including: laproscopic procedures for ovarian problems between 1971 and 1981; a cesarean section birth in 1981; appendix removal in 1983; gallbladder removal in 1985; bladder lift in 1987; three to four hernia repairs in 1997; a cervical hysterectomy in 1997; ovary removal in 1999; vertical banding and stomach stapling in 2003; a second bladder lift in 2005; large hernia repair in 2005; and a cystocele presumably in 2005. (Defs.' Mem. Supp. Mot. Summ. J., Ex. A, Lynn Garrity Dep., 26:13-18, Jun. 5, 2008 ("Garrity Dep.").)<sup>1</sup>

In the spring or summer of 2004, Plaintiff's husband purchased a Pain Relief System from a CVS pharmacy in Yeadon, Pennsylvania. (<u>Id.</u> at 26:12-19.) Although her husband needed only a cold pack at the time, he purchased the Pain Relief System to keep the Hot Pack for possible future use. (<u>Id.</u> at 26:20-27:8.)

Plaintiff first used the Hot Pack portion of the product on September 12, 2005. (<u>Id.</u> at 37:5-11.) She had just had an abdominal seroma aspirated from her stomach, causing a hematoma to form. Her doctor advised her to massage it and use a hot pack on her stomach. (<u>Id.</u> at 37:14-38:16.) As such, she went home that day and pulled the Hot Pack at issue out of its box, which had been stored in a dark closet. (<u>Id.</u> at 39:6-20.) The box contained both the red gel Hot Pack, as well as a white sleeve into which the Hot Pack goes after heating. (<u>Id.</u> at 39:22-40:1.) The blue cold pack was in the freezer. (<u>Id.</u> at 40:2-5.) Plaintiff read the outside of the box, which said, "See complete instructions inside package before using." (<u>Id.</u> at 34:24-35:5.)

Plaintiff did not read and, in fact, was not aware of any folded, four-page user instruction

<sup>&</sup>lt;sup>1</sup> Plaintiff was remarried following the death of her first husband. Her deposition was taken, and is thus titled, under her married name.

pamphlet that was purportedly included with the product. (Id. 26:19-27:4, 28:23-30:15, 65:20-

25.) The instruction book warned, in pertinent part:

Apply to painful area. Hold in place with elastic strap and Velcro tape. Check skin under pack frequently to avoid burning or blistering.

Do not use on insensitive skin, on a helpless person, a person with diabetes or a person with poor blood circulation.

Do not apply directly to skin. Always use cloth cover. Burns may occur.

(Defs.' Mem. Supp. Mot. Summ. J., Ex. E.)

Inside the box, on the back of the red Hot Pack, however, were another set of two instructions – one for use in hot water and one for use in a microwave. The "Hot Water" instructions stated:

HOT WATER (SEE INSTRUCTION BOOK FOR DETAILED INSTRUCTIONS) Bring at least 3 quarts of water to a rolling boil. Remove water from heat and immerse Hot Pack for no more than 7 minutes. Use kitchen tongs to remove pack from water. Use Heat Guide as described below. Place pack in cover and apply to painful area.

#### CAUTION:

- 1. Follow all directions for use
- 2. Do not use when Heat Guide reads TOO HOT, burns may occur.
- 3. Always use cloth cover. Do not apply Hot Pack directly to skin, burns may occur.
- 4. Do not use on insensitive skin.
- 5. Discard immediately if punctured or torn.
- 6. Gel is not intended for ingestion.
- 7. Keep out of reach of children. Adult supervision recommended if used by a child. Do not use on infants.

(Pl.'s Opp. Mot. Summ. J., Ex. B.) Immediately below the "Hot Water" instructions and related caution section, was another heading entitled "Microwave" with its own set of instructions and warnings:

MICROWAVE: Lay hot pack flat in microwave with heat guide up. Heat at full power 700 watts for 60 seconds. Remove from microwave and check heat guide. Heat level low/medium/high is indicated by the appearance of green around the word. Pack is too hot for use when too hot is visible in red against a black background. If additional heat is desired, re-place in microwave and heat in 10 second intervals. Remove and read heat guide.

CAUTION: Do not heat pack for more than 90 seconds at one time. Excessive heating may cause pack to rupture and leak. Place pack in cloth cover and apply to painful area. After one hour, hot pack may be reheated in 30-second intervals. Remove and read heat guide.

(<u>Id.</u> at 34:4-20; Pl. Opp. Mot. Summ. J., Ex. B.) Plaintiff did not read any of the instructions under the "Hot Water" section. (Garrity Dep. at 36:10-18.) Plaintiff did, however, read the directions located immediately below the above-described instructions and under the heading "Microwave." (<u>Id.</u> at 33:11-16.)

Upon reading these directions, Plaintiff put on her pajamas and took ten milligrams of Percocet for pain relief. (Id. at 40:19-41:4.) Notably, Plaintiff also had a lidocaine injection in her stomach area during the aspiration procedure. (Id. at 43:1-9.) She took the Hot Pack and put it in her 800 watt microwave for thirty seconds. (Id. at 44:21-45:1.) When she took it out, she noted that it felt nice and comfortable, and that green had appeared around the word "medium." (Id. at 45:2-5.) She flattened out the gel pack to ensure that there were no leaks and then put it in the enclosed sleeve. (Id. at 45:1-46:3.) Thereafter, she laid on the couch in the living room and placed the sleeve on top of her skin, underneath her pajama shirt. (Id. at 46:4-12.) During the first three minutes, the Hot Pack kept sliding off her stomach. (Id. at 46:13-19.) At her husband's suggestion, she wrapped it up in a kitchen towel and held it on to her abdomen. (Id. at 46:20-47:15.) She testified that although she could not feel a lot of the warmth, the heat "felt good." (Id. at 47:14-19.)

After about thirty-five to forty-five minutes of using the Hot Pack, she went upstairs to take a shower. (Id. at 47:23-48:23.) When she removed the pack, she noticed some red stuff, about the size of a quarter, on the dish towel. (Id. at 49:1-3, 77:18-21.) Her husband commented that she had a purple burn mark and blister on the left side of her stomach. (Id. at 49:3-9.) There were also burns where her fingerprints and palm of her hand were holding the pack. (Id. at 49:11-25.) She felt no pain, however, until the air hit the burn. (Id. at 50:8-18.) At that point, she changed her clothes and drove herself to the emergency room at Crozer-Chester Hospital in Delaware County, Pennsylvania. (Id. at 50:1-51:11.) The emergency room doctors told her that she had second or third degree burns, treated her with pain medication and a cream, and instructed her to make an immediate appointment with the Crozer-Chester Burn Center for treatment. (Id. at 51:12-19.) At the Burn Center, she was unsuccessfully treated with multiple skin grafts. (Id. at 52:3-25.) On October 5, 2005, she underwent surgery for full removal of the burn, and was hospitalized for three to five days. (Id. at 52:21-53:9.)

#### **B.** The Expert Reports

#### 1. Kenneth G. Swan, M.D.

Kenneth G. Swan, M.D., a professor of surgery at the University of Medicine and Dentistry of New Jersey, issued a report, on May 19, 2008, summarizing Plaintiff's care for her burn. He concluded that,

[T]he patient sustained a full thickness skin and subcutaneous tissue loss of a sizable portion of her anterior abdominal wall as a result of the "hot pack" which she applied to her abdomen on 12 September 2005. In all probability the multiple surgical procedures on her abdomen compromised sensory innervation of the area, rendering it compromised in terms of sensation and therefore pain perception, allowing the hot pack to cause this damage unbeknownst to the patient.

(Pl.'s Opp. Mot. Summ J., Ex. E.)

During her deposition, however, Plaintiff disagreed with Dr. Swan's assessment. (Garrity Dep. at 61:21-63:8). Accordingly, Dr. Swan issued an "appended report" concluding that Plaintiff had "no loss of sensation in the region of her abdomen where the hot pack was applied." (Pl.'s Opp. Mot. Summ. J., Ex. E.) Dr. Swan went on to render the following opinion:

[Plaintiff] indicate[d] that she had taken Percocet for relief of pain, but insisted that the cutaneous sensation in her abdomen at the time, in that location, was not, as a result impaired.

\* \* \*

[M]ention must be made of the fact that local anesthetics were used to facilitate needle aspiration of the seroma by Dr. Raezer the day of the burn. The time elapsed after the use of Xylocaine and before use of the hot pack would indicate to me that there were no residual effects of the Xylocaine. Furthermore, and the patient has told me, as mentioned, that the cutaneous sensation was intact and not compromised by any medication at the time of hot pack use.

Finally, the patient's diabetes is relevant regarding possible peripheral neuropathy being present to account for the possibility of diminished sensation. I tested the patient for her response to light touch and superficial pain. Finding none of these responses abnormal, I concluded that there was no detectable neuropathy.

(<u>Id.</u>)

#### 2. Robert Schiffman

Robert Schiffman, an expert on issues relating to microwave ovens and their use, also prepared a report regarding the various issues involved in this case. (Defs.' Mem. Supp. Mot. Summ. J., Ex. H.) Mr. Schiffman first opined that there was no listing of the microwave power anywhere on Plaintiff's microwave oven – a fairly common omission. (Id. at 5.) Following testing, he determined that, although Plaintiff's microwave oven would be characterized as an 800 watt oven, the microwave's output varied from 791 watts to 822 watts over the course of a single day. (Id.)

Mr. Schiffman next ran various tests on the Hot Pack, after which he drew several conclusions. First, he noted that temperatures at various locations on the Hot Pack were dangerously high and likely to cause injury. (Id. at 15.) Second, he commented that temperatures were uneven across the pouch. (Id.) Third, he noted that, in some tests, even though the Heat Guide temperature sensor read "LO" or "MED," the actual temperatures exceeded 150 degrees farenheit. (Id.) Fourth, he found that the location of the temperature sensor was often remote from the highest temperature. (Id.) Fifth, he observed that the temperature at the skin increased with time - a phenomenon unique to microwave heating and resulting from the properties of the gel packs themselves. (Id.) Sixth, he remarked that upon multiple heatings of the Hot Pack, the pack ruptured and the gel oozed out of the pouch. (Id. at 10-11.) Finally, he found that the heat guide itself was flawed in indicating the correct temperature of the gel. (Id. at 19-20.)

Next, Mr. Schiffman studied the terry cloth cover included with the Hot Pack. He found that the pouch often does not cover the entire gel pack. (<u>Id.</u> at 20.) In addition, he remarked that the pouch is difficult to use because it is a tight fit and because the gel pack is hot and uncomfortable to handle. (<u>Id.</u>)

Finally, Mr. Schiffman addressed the various warnings and instructions. He noted the following in particular:

- C. The Heating Instructions: Despite heating instructions existing on the gel pack, on the exterior of the carton, and on the insert brochure in the carton, there are ambiguities and omissions that could easily cause injury:
  - The product should never be used for children and seniors. Reference is made to the 3rd degree burns in Table 3.
  - The gel pack should be thoroughly dry when placed in the cloth pouch; otherwise the heat transfer through the wet

areas is greatly increased. Note that consumers are advised to rub the heat sensor with an ice cube – that will wet the surface.

- Consumers are told to gently "knead the gel to evenly distribute heat." But the gel is not a liquid, therefore, heat can't be transferred that way and will not become uniform. It will only be possible to push gel into empty areas inside the polyethylene pouch.
- D. While the consumer is told, in all three locations noted above, that the gel pack is reusable, no suggestion is given as to how many times it can be reused. In my tests I had two gel pack ruptures following single use for each gel pack.
- E. There are not instructions on how the product should be stored: Freezing or rapid cooling and/or storage in a refrigerator are likely to damage the gel's water holding capacity and release free water which later can form steam and rupture the pouch and even burn the consumer.
- F. The instruction to: "Heat at full power (700 watts) for 60 seconds" is seriously flawed for many reasons and suggests an ignorance of microwave ovens, what they are and how they operate. For example:
  - 700 watts represents only a small percentage of the ovens in consumers' homes. "Full Power" varies from 400 to over 1200 watts.
  - Indicating 700 watts is also without merit because, as has been determined in numerous studies, most consumers have no idea what the wattage of their ovens are. Nor can they easily find out as demonstrated with Ms. Street's oven where no power listing is given anywhere on the oven.
  - 700 watts is also meaningless in the sense that not all 700 watt ovens are alike, and further, that the 700 watts is an averaged number at the factory for a given model which is likely to vary by at least 15% around this average (i.e. 595 to 805 watts). What is really of importance is how many watts are available to heat an object such as the gel pouch whose weight is on the order of 160 grams. Only a small but varying percentage of Full Power, on the order of 100 watts, will be available to heat the pouch. So some microwave

ovens will heat it faster, some slower.

(<u>Id.</u> at 21-22.)

Ultimately, Mr. Schiffman concluded that the Pain Relief System was a seriously flawed product that should never be heated in a microwave oven, due to (1) the uneven and inconsistent heating of the gel packs; (2) the constantly rising temperature of the pack after placed on the skin; and (3) the instability of the gel. (Id. at 22.) He remarked that, on September 12, 2005, Plaintiff had been burned by the Hot Pack and/or by the gel that leaked from the Hot Pack. (Id. at 24.)

#### 3. Ezra Krendel

Finally, Ezra S. Krendel, Plaintiff's warnings expert, opined on the adequacy of the warnings supplied on the Pain Relief System. (Def. Mem. Opp. Mot. Summ. J., Ex. I.) Primarily, he indicated that the manner in which the instructions were provided by the product packaging caused the product to be unsafe and dangerous, since the word "CAUTION" was not displayed in an attention commanding format and color. (Id. at 4-5.) Second, he stated that the distributor should consider that a pamphlet either might not be provided in the box or might be misplaced by consumer, especially with a reusable product. (Id. at 5.) Third, he remarked that the box and/or the red gel hot pack did not warn against use by a diabetic. (Id.) Fourth, he opined that the box and/or the red gel hot pack did not warn the consumer to check the skin under the pack frequently to avoid burning or blistering. (Id.) Finally, he stated that neither the pamphlet, the box nor the red gel Hot Pack warned the consumer not to take pain relieving medications prior to using the product. (Id. at 6.)

#### C. Procedural History

Plaintiff filed this federal action on July 5, 2007. In her Complaint, Plaintiff alleges

negligence (Count I), strict liability (Count II) and breach of warranty (Count III). (Compl. ¶¶ 27-35.) On July 8, 2008, Defendants moved for summary judgment on all counts.

#### II. STANDARD OF REVIEW

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c). A factual dispute is "material" only if it might affect the outcome of the case.

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S. Ct. 2505, 2510 (1986). For an issue to be "genuine," a reasonable fact-finder must be able to return a verdict in favor of the non-moving party. Id.

On summary judgment, it is not the court's role to weigh the disputed evidence and decide which is more probative, or to make credibility determinations. Boyle v. County of Allegheny, PA, 139 F.3d 386, 393 (3d Cir. 1998) (citing Petruzzi's IGA Supermarkets, Inc. v. Darling-Delaware Co. Inc., 998 F.2d 1224, 1230 (3d Cir. 1993). Rather, the court must consider the evidence, and all reasonable inferences which may be drawn from it, in the light most favorable to the non-moving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S. Ct. 1348 (1986) (citing United States v. Diebold, Inc., 369 U.S. 654, 655, 82 S. Ct. 993 (1962)); Tigg Corp. v. Dow Corning Corp., 822 F.2d 358, 361 (3d Cir. 1987). If a conflict arises between the evidence presented by both sides, the court must accept as true the allegations of the non-moving party, and "all justifiable inferences are to be drawn in his favor." Anderson, 477 U.S. at 255.

Although the moving party bears the initial burden of showing an absence of a genuine

issue of material fact, it need not "support its motion with affidavits or other similar materials negating the opponent's claim." Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S. Ct. 2548, 2553 (1986). It can meet its burden by "pointing out . . . that there is an absence of evidence to support the nonmoving party's claims." Id. at 325. Once the movant has carried its initial burden, the opposing party "must do more than simply show that there is some metaphysical doubt as to material facts." Matsushita Elec., 475 U.S. at 586. "There must . . . be sufficient evidence for a jury to return a verdict in favor of the non-moving party; if the evidence is merely colorable or not significantly probative, summary judgment should be granted." Arbruster v. Unisys Corp., 32 F.3d 768, 777 (3d Cir. 1994), abrogated on other grounds, Showalter v. Univ. of Pittsburgh Med. Ctr., 190 F.3d 231 (3d Cir. 1999).

#### III. DISCUSSION

#### A. Strict Liability

Defendants first seek summary judgment on Plaintiff's claim of strict liability. Section 402A of the Restatement (Second) of Torts,<sup>2</sup> which was adopted by the Supreme Court of

<sup>&</sup>lt;sup>2</sup> Section 402A provides:

<sup>(1)</sup> One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

<sup>(</sup>a) the seller is engaged in the business of selling such a product, and

<sup>(</sup>b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

<sup>(2)</sup> The rule stated in Subsection (1) applies although

<sup>(</sup>a) the seller has exercised all possible care in the preparation and sale of his product, and

<sup>(</sup>b) the user or consumer has not bought the product from or entered into

Pennsylvania in Webb v. Zern, 220 A.2d 853, 854 (1966), "imposes strict liability for injuries caused by defective product design." Pacheco v. Coats Co., Inc., 26 F.3d 418, 421 (3d Cir. 1994) (citing Lewis v. Coffing-Hoist Div., Duff-Norton Co., 528 A.2d 590, 592 (Pa. 1987)). Section 402A "requires only proof that a product was sold in a defective condition unreasonably dangerous to the user or consumer, and that the defect was the proximate cause of plaintiff's injuries." Parks v. AlliedSignal, Inc., 113 F.3d 1327, 1330-31 (3d Cir. 1997) (quoting Walton v. Avco Corp., 610 A.2d 454, 458 (Pa. 1992)).

The determination as to whether a product is "unreasonably dangerous" is a threshold question of law that must be resolved by the court. Moyer v. United Dominion Indus., Inc., 473 F.3d 532, 538 (3d Cir. 2007) (citing Azzarello v. Black Bros. Co., 391 A.2d 1020, 1026 (Pa. 1978)). "If the judge concludes that a product is 'unreasonably dangerous' the case is submitted to the jury, which then decides, based on all the evidence presented, 'whether the facts of the case support the averments of the complaint." Id. at 538-39 (quoting Azzarello, 391 A.2d at 1026). In making this latter determination, the jury does not balance the risk-utility factors, but rather considers whether the product "left the supplier's control lacking any element necessary to make it safe for its intended use or possessing any feature that renders it unsafe for the intended use."

Id. (quoting Phillips v. Cricket Lighters, 841 A.2d 1000, 1005 (Pa. 2003).

Relying on the foregoing standards, Defendants argue that Plaintiff's strict liability claim must be denied on two bases. First, they contend that the Hot Pack was not "unreasonably dangerous" as a matter of law. Second, they allege that Plaintiff cannot prove causation. The

contractual relations with the seller.

RESTATEMENT (SECOND) OF TORTS § 402A (1965).

Court addresses each argument separately.

## 1. Whether the Hot Pack Was Unreasonably Dangerous

The Pennsylvania Supreme Court, in formulating the threshold "unreasonably dangerous" standard, emphasized that the decision was one of social policy:

Should an ill-conceived design which exposes the user to the risk of harm entitle one injured by the product to recover? Should adequate warnings of the dangerous propensities of an article insulate one who suffers injuries from those propensities? When does the utility of a product outweigh the unavoidable danger it may pose? These are questions of law and their resolution depends upon social policy.

Azzarello, 391 A.2d at 1026. Thereafter, the Pennsylvania Superior Court explained that "a court must possess the qualities of both a social philosopher and a risk-utility economic analyst," in order to "balance 'the utility of the product against the seriousness and likelihood of the injury and the availability of precautions that, though not foolproof, might prevent the injury." Fitzpatrick v. Madonna, 623 A.2d 322, 324 (Pa. Super. 1993) (quoting Burch v. Sears, Roebuck & Co., 467 A.2d 615, 618 (Pa. Super. 1983)).

In <u>Surace v. Caterpillar, Inc.</u>, 111 F.3d 1039 (3d Cir. 1997), the United States Court of Appeals for the Third Circuit interpreted the unreasonably dangerous standard in an effort to provide guidance to trial judges. Applying Pennsylvania law, the Third Circuit held that "the question for the court to determine is whether the evidence is sufficient, for purposes of the threshold risk-utility analysis, to conclude as a matter of law that the product was not unreasonably dangerous, not whether the evidence creates a genuine issue of fact for the jury." <u>Id.</u> at 1049 n. 10. The court enumerated seven factors (the "Wade factors")<sup>3</sup> relevant to this analysis:

<sup>&</sup>lt;sup>3</sup> These factors were first set forth in a law review article authored by Dean John Wade. <u>See</u> Wade, "On the Nature of Strict Tort Liability for Products," 44 Miss. L.J. 825 (1973).

- (1) The usefulness and desirability of the product-its utility to the user and to the public as a whole;
- (2) The safety aspects of the product the likelihood that it will cause injury, and the probable seriousness of the injury;
- (3) The availability of a substitute product which would meet the same need and not be as unsafe;
- (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility;
- (5) The user's ability to avoid danger by the exercise of care in the use of the product;
- (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instruction; and
- (7) The feasibility, on the part of the manufacturer, of spreading the loss of [sic] setting the price of the product or carrying liability insurance.

<u>Id.</u> (quoting <u>Dambacher v. Mallis</u>, 485 A.2d 408, 423 n.5 (Pa. Super. 1984)).

Using these Wade factors, the trial judge must determine whether a product is unreasonably dangerous "under a weighted view of the evidence, considering the facts in the light most favorable to the plaintiff." Moyer, 473 F.3d at 538 (citing Phillips v. A-Best Prod. Co, 665 A.2d 1167, 1171 n.5 (Pa. 1995)). In the course of weighing these factors, the Court must also keep in mind the purpose of the product. As explained by the Pennsylvania Superior Court:

Determining the product's intended purpose is critical to the court's legal conclusions about whether the product can be deemed defective. The court will necessarily make different conclusions about the risk-utility of a product depending on whether the court construes the intended purpose of a product broadly or narrowly. If the trial court is properly to discharge its duty as a social philosopher and a risk-utility economic analyst, the court must be afforded some measure of latitude to determine the intended purpose of a product. It follows that the intended use of a product is a conclusion of law, to be decided by the trial court. In

other words, the trial court is not bound by any party's legal conclusions as to the intended purpose of a product, even if those conclusions are couched as averments of fact or presented as expert evidence. To hold otherwise would force trial courts (and reviewing courts) to accept unrealistic, generalized, or distorted views of a product's purpose simply because they are presented as factual evidence.

Schindler v. Sofamor, Inc., 774 A.2d 765, 773 (Pa. Super. 2001) (citations and footnotes omitted). If the judge determines as a matter of law "that the risk-utility balance so favor[s] the manufacturer that the [product] could not be deemed unreasonably dangerous," then the claim does not go to the jury. Surace, 111 F.3d at 1048. Notably, it is a defendant's burden to establish, as a matter of law, that its product was not unreasonably dangerous. See Bleyer v. Illinois Tool Works, Inc., Civ. A. No. 02-729, 2002 WL 32341782, at \*4 (E.D. Pa. Dec. 30, 2002).

Plaintiff identifies four alleged defects in the Heat Pack at issue, which purportedly render it "unreasonably dangerous." First, she claims that the instructions on the product were defective since (a) the instruction to knead the product would not evenly distribute the gel and (b) the instruction to heat the gel "full power (700 watts) for 60 seconds" does not account for the facts that most consumers do not know the wattage and, in any event, 700 watt microwaves often vary by 15% (595 to 805 watts). Second, she alleges that Defendants should never have recommended that the Hot Pack be heated in the microwave due to both the uneven heating propensities of microwaves and the fact that they quickly heat, leaving insufficient time for conductive heat transfer with the gel. Third, Plaintiff asserts that the gel itself was defective because it was not stable and was subjected to deterioration and breakdown, eventually causing the water steam to expand and rupture the gel pack. Finally, she contends that, as a result of the uneven heating of the gel, the Hot Pack's heat guide did not reflect the actual temperature of some portions of the heated gel, even when heated only thirty seconds. (Pl.'s Opp. Mot. Summ. J. 14-15.)

In light of these allegations, it becomes incumbent upon this Court to apply the Wade factors to this case and determine whether the Hot Pack was unreasonably dangerous as matter of law.<sup>4</sup>

# a. <u>Usefulness and Desirability of the Product – Its Utility to the</u> User and to the Public as a Whole

The first Wade factor focuses on whether the Hot Pack, as a whole, was useful and desirable – not whether any of the allegedly defective parts were useful. <u>Kagan v. Harley Davidson, Inc.</u>, Civ. A. No. 07-694, 2008 WL 3874824, at \*7 (E.D. Pa. Aug. 20, 2008) (citing <u>Epler v. Jansport, Inc.</u>, Civ. A. No. 00-154, 2001 WL 179862, at \*3 (E.D. Pa. Feb. 22, 2001)). Defendant argues that the Hot Pack is helpful to both its user and to the public as a whole.

The Court agrees. Plaintiff expressly testified that she believed the Heat Pack would be useful to her.

- Q. And what made you buy a heating pack?
- A. Actually, we bought it for the cold pack. Not we. Excuse me. Myself and my husband that passed away, he had Crohn's disease and he had some inflammation with a back injury, so we needed to get a cold pack. And when we went to CVS, he saw a hot and cold pack. And he thought that might be a good thing to use in case we ever need the hot pack. We'll just use the cold pack instead of buying two different ones. And it was in a box. It was convenient. So we decided to go with the hot and cold pack.

(Garrity Dep. 26:20-27:8.) Plaintiff went on to state that her doctor prescribed use of a hot pack after her surgical procedure in September 2005:

A. I had just had my stomach – I was getting what they call abdominal seroma

<sup>&</sup>lt;sup>4</sup> Notwithstanding Defendants' thorough review of each of the Wade factors, Plaintiff fails to engage in a similar analysis and cites only to 1966 and 1975 cases from the Pennsylvania Supreme Court. The controlling <u>Azzarello</u> standard, however, was not issued until 1978, making Plaintiff's case citations obsolete. The Court nonetheless takes into account Plaintiff's arguments and considers the facts relevant to each factor in light most favorable to Plaintiff.

taken from my stomach, aspirated with a long needle at Dr. Razer's office for buildup of fluid in my abdomen.

\* \* \*

And I was getting it drained three times a week and my stomach was hurting really bad. And a hematoma built up under the skin and it was painful. And he had given me my prescription for my pain medication, and he told me to get a hot pack and put it on my abdomen and try to massage it in so that the hematoma might break up so they could get the fluid that was resting underneath the hematoma.

(Id. at 37:14-38:9.)

Moreover, as Defendants accurately point out, the Hot Pack is useful to the public as a whole. The Food and Drug Administration ("FDA") has recognized hot and cold packs as physical medicine therapeutic devices. 21 C.F.R. § 890.5710. Moreover, Richard John Prins, Senior Director Product Safety Engineer for Sunbeam Products, testified that Sunbeam sold the Pain Relief System for approximately ten years and that, in the four years that it purchased it from Cryopak, Sunbeam bought somewhere between 75,000 and 100,000 units. (Defs.' Mem. Supp. Mot. Summ. J. Ex. B, Richard John Prins Dep., 19:23-20:24, Jun. 4, 2008 ("Prins Dep").) Such figures evidence the product's social utility. Accordingly, the Court find that this factor weighs in favor of Defendants.

# b. <u>The Safety Aspects of the Product - the Likelihood that it Will</u> <u>Cause Injury, and the Probable Seriousness of the Injury</u>

The second factor requires inquiry into the safety aspects of the product at issue, and focuses on the likelihood that the product will cause injury, and the probable seriousness of any injury caused. Kagan, 2008 WL 3874824, at \*8. "In connection with this analysis . . . a product must be safe for its 'intended use,' and that term includes 'any use which is reasonably foreseeable to the seller.'" Bowersfield v. Suzuki Motor Corp., 111 F. Supp. 2d 612, 620 (E.D.

Pa. 2000) (quoting Parks v. Alliedsignal, Inc., 113 F.3d 1327, 1331 (3d Cir. 1997)). "The mere fact that a product may cause injury does not, however, lead to the conclusion that it is 'unreasonably dangerous' as a matter of law." Warnick v. NMC Wollard, Inc., 512 F. Supp. 2d 318, 326 (W.D. Pa. 2007). "It is appropriate to consider the actual rate of injuries caused by a particular product" when considering the second factor in the risk-utility analysis. Lancenese v. Vanderlans and Sons, Inc., Civ. A. No. 05-5951, 2007 WL 1521121, at \*3 (E.D. Pa. May 21, 2007). In other words, "the relevant inquiry is the overall likelihood of injuries and the seriousness of the injuries, not whether one or two people suffered serious injuries." Kagan, 2008 WL 3874824, at \* 9.

Defendant argues that the Hot Pack was not likely to cause serious injury on several grounds. First, it contends that the FDA has classified a hot pack as a low risk device. See 21 C.F.R § 890.5710. Second, it asserts that when the Hot Pack is heated in a microwave consistently with its directions, it does not become dangerously hot. Finally, as to Plaintiff's allegation that the heat indicator on the Hot Pack did not function properly, Defendant argues that an individual who heats an item in a microwave should know that the product may come out hot, "if not by common sense – then by touch." (Defs.' Mem. Supp. Mot. Summ. J. 18.)

Notwithstanding Plaintiff's failure to counter with any statistical evidence regarding the rate of injuries caused by either the Hot Pack at issue or similar hot packs, the Court finds that the evidence, taken in the light most favorable to Plaintiff, suggests that the Hot Pack, as marketed and sold by Defendants, had a significant likelihood to cause serious injury. The intended use of the Hot Pack was for pain relief. Plaintiff heated the Hot Pack for less than the recommended time, engaged in the intended use of the Hot Pack at the direction of her physician, yet suffered

second or third degree burns. According to Mr. Schiffman, there was no safe way to heat the Hot Pack in a microwave because of the uneven heating propensities of the gel – potentially leaving the Hot Pack comfortable to the touch in some areas, but excessively hot in others. That danger was compounded by the facts that (1) the heat indicator – designed to warn a user of a dangerously hot Hot Pack – could mislead a user into believing the Hot Pack was safe; and (2) the gel pack could easily rupture following microwave heating, burning a user's skin. Assuming all these facts to be true, any such Hot Pack heated in a microwave would have an overall likelihood to cause similarly serious injuries to its intended users.

c. The Availability of a Substitute Product Which Would Meet the
Same Need and Not Be as Unsafe (Factor 3) and the
Manufacturer's Ability to Eliminate the Unsafe Character of
the Product Without Impairing its Usefulness or Making It Too
Expensive to Maintain Its Utility (Factor 4)

The third factor and fourth factors merit joint discussion. The third factor demands "an analysis of the availability of a substitute product that would meet the same need as the [product at issue] and would not be as unsafe as the [product at issue]." Kagan, 2008 WL 3874824, at \*9. "The proposed alternative design must be 'safer overall." Van Buskirk ex rel. Van Buskirk v. West Bend Co., 100 F. Supp. 2d 281, 287 (E.D. Pa. 1999) (quoting Riley v. Becton, 913 F. Supp. 879, 886 (E.D. Pa. 1995)). Defendants argue that, "Plaintiff has offered no evidence during discovery of a substitute component or product which would meet the same need as the Hot Pack be safer overall." (Defs.' Mem. Supp. Mot. Summ. J. 19.) While true, "the burden is not on plaintiffs to set forth affirmative evidence to rebut defendant's motion." Cutshall v. Photo Medic Equip., Inc., 2000 WL 1028548, at \*5 (M.D. Pa. 2000) (rejecting argument that plaintiffs must present evidence of available and safer substitute products in rebuttal to summary judgment).

In any event, Plaintiff's case is less about the availability of a safer substitute product, and more about Defendants' ability to eliminate the unsafe character of the product without impairing its usefulness or making its price prohibitive, under the fourth factor. Bowersfield v. Suzuki Motor Corp., 111 F. Supp.2d 612, 620-21 (E.D. Pa. 2000). Sufficient evidence exists to show that the Hot Pack could have been made significantly safer. As noted above, Plaintiff's expert, Mr. Schiffman, opined (1) that the Heat Pack should never be heated in a microwave oven, since microwaves heat unevenly and too quicky to allow for conductive heat transfer and (2) that the gel pack design subjects it to a high risk of rupture, despite the statement that the Hot Pack is reusable. (Pl.'s Opp. Mot. Summ. J., Ex. F, 22.) In addition, Plaintiff's expert, Mr. Krendel<sup>5</sup> opined (1) that all crucial warnings should have been placed on either the box or the actual gel pack; (2) neither the gel pack nor the box warned against use by a diabetic; (3) neither the box nor the gel pack warned the consumer to check the skin under the pack frequently to avoid burning or blistering; and (4) neither the pamphlet, box or gel back warned about taking pain relief medications prior to using the product.

None of these proposed alterations would either impair the usefulness of the product or make it too expensive. Eliminating any directions for heating in a microwave oven would resolve many of the problems identified by Mr. Schiffman, but still allow the Hot Pack to be heated by hot water. Similarly, the addition of the various warnings onto either the gel pack itself or the box would neither affect the use of the product nor be economically prohibitive.

<sup>&</sup>lt;sup>5</sup> Defendants' statement that "Krendel's report should not be considered because he did not cite to any tests or any specific literature that would show that these three warnings would have made the Hot Pack safer" appears to be a request that Court exclude Krendel's expert report. (Def. Mem. Supp. Mot. Summ. J. 20.) Such a request, however, should be made by a properly filed <u>Daubert</u> motion and is not adequately argued here.

Defendants do not challenge Mr. Schiffman's suggestion that the product not be heated via microwave. They do, however, object to each of the warnings proposed by Mr. Krendel.

Considering each of Defendants' challenges individually, the Court does not find Mr. Schiffman's proposed warnings either unfeasible or ineffective as a matter of law.

First, Defendants contend that Plaintiff admitted that she did not read the existing warnings on the Hot Pack and, thus, likely would not have read any additional proposed warnings. As is clear to this Court, however, the caution warnings about which she was asked, at her deposition, were listed under the "CAUTION" section for the "Hot Water" heating instructions – a section Plaintiff conceded she did not read because she was not heating the pack using hot water. The "Microwave" heating instructions had their own separate "CAUTION" section, which, by all accounts, was heeded by Plaintiff. Logical inference suggests that Plaintiff would have similarly heeded any new instructions placed in this section.

Second, Defendants contend that all of the warnings proposed by Mr. Schiffman are either patently obvious (warning about non-use of pain relief products in conjunction with the Hot Pack), or do not make the product safer (warning that an individual should frequently check their

<sup>&</sup>lt;sup>6</sup> Specifically, Plaintiff testified as follows:

Q. Looking at the red gel pack, I asked you whether you read any of the information contained under Hot Water and you said no; is that correct?

A. That's correct.

Q. Under Hot Water but above Microwave, there are seven paragraphs or sentences under the heading Caution. Did you read those?

A. No I did not.

skin under the Hot Pack). The Court again finds no merit to this claim. As to the first warning, the use of pain medication was not unforeseeable. Sunbeam, by admission of its own representative, was aware that people who have had surgery might use the product. (Pl. Opp. Mot. Summ. J., Ex. H, Richard Prins Dep., 57:21-24, Jun. 4, 2008 ("Prins Dep.").) Making the logical next step, Defendant should have also known that a person who recently underwent surgery might also take pain medication. Thus, a warning that pain medication should not be used in conjunction with the Hot Pack, for fear of dulling any burn sensation, would not be patently obvious and would possibly eliminate the danger faced by Plaintiff. See Perez v. Townsend Engineering Co., Civ. A. No. 05-2337, 2008 WL 614784, at \*8 (M.D. Pa. Mar. 5, 2008) ("A product may be deemed defective where it lacks adequate warnings or instruction necessary for the safe use of the product.").

The Court likewise finds no merit to Defendants' obviousness challenge to the third proposed warning – that the user should check their skin under the Hot Pack frequently to avoid burning or blistering. While such an addition would not eliminate the danger, it would certainly render the product safer. "The court must balance 'the utility of the product against the seriousness and likelihood of the injury and the availability of precautions that *although not foolproof*, might prevent the injury." Surace v. Caterpillar, 111 F.3d 1039, 1049-50 (3d Cir. 1997) (quoting Burch v. Sears, Roebuck and Co., 467 A.2d 615, 618 (Pa. Super. 1983)).

Finally, Defendants argue that Krendel has not identified where on the small Hot Pack or on the box his proposed warnings should appear, what effect any font reduction would have on the impact of the warnings, why the proposed warnings need not appear on both the box and the Hot Pack itself, or what the cost-benefit analysis of the additional warnings would be. Such arguments

disregard the standard on a motion for summary judgment. Defendants have produced no evidence or made no arguments to show an *absence* of a genuine issue of material fact. <u>Celotex v.</u> <u>Catrett</u>, 477 U.S. 317, 323, 106 S. Ct. 2548, 2553 (1986). Rather, they have raised a series of questions about Mr. Krendel's report that highlight to this Court the unequivocal existence of a factual issue that cannot be resolved during summary judgment proceedings.

In short, the Court finds that Plaintiff has offered sufficient alternatives in design that would eliminate the unsafe character of the Hot Pack without impairing its usefulness.

Defendants' challenges to those proposals, while not necessarily incorrect, involve issues of fact that now require the considered attention of a jury. Accordingly, the Court weighs these factors in favor of Plaintiff.

## d. The User's Ability Avoid Danger by the Exercise of Care in the Use of the Product

"The proper focus in applying the fifth Wade factor . . . is an objective inquiry into whether the class of ordinary purchasers of the product could avoid injury through the exercise of care in use of the product, not whether this particular plaintiff could have avoided this particular injury." Surace, 111 F.3d at 1051. "Put differently, the user's ability to avoid injury by the exercise of care in the use of the product appears to be a design factor that may justify a more or less exacting design depending on the facts, but it is, in any case, not a vehicle for injecting a plaintiff's (alleged) failure to exercise due care into the case." Id. "The analysis does not center on the due care *vel non* of the consumer but rather highlights whether a product is duly safe for its intended use." Id. at 1052 (quotations omitted).

Defendants argue that an average product user could avoid any danger posed by the Hot Pack by using common sense and following its instructions and warnings, including those

contained on the pamphlet inside the box. They contend:

The directions include heating the Hot Pack for 60 seconds in a 700 watt microwave, waiting 20-30 seconds before checking the heat guide, applying the pack to the painful area, holding it in place with an elastic strap and Velcro tape, and checking one's skin under the pack frequently to avoid burning or blistering. A person with insensitive skin, a helpless person, a person with diabetes, or a person with poor blood circulation would not use the pack. Plaintiff . . . can identify no evidence that the Hot [Pack] places an individual who followed all of the directions associated with the product – and used common sense during the process – would face any danger.

(Def. Mem. Supp. Mot. Summ. J. 23.)

Defendants' argument, however, fails in several respects. First, it pays no heed to the report of Mr. Schiffman, which opines that the gel Hot Pack could not be safely heated in a microwave, under any conditions, due to the uneven heating propensities of both a microwave and the gel itself, and due to the distinct possibility that the gel pack would rupture in a microwave.

Second, it neglects to consider that an objective person not being otherwise warned may take pain medication in conjunction with use of the Hot Pack, which might disguise any burning sensation.<sup>7</sup>

<sup>&</sup>lt;sup>7</sup> Defendants argue that the Hot Pack warned against use on insensitive skin and that pain relief medication would necessarily make one's skin insensitive. As Sunbeam's own representative testified, however, the definition of insensitive is rather broad. It does not clearly include a person on pain medication whose skin sensitivity may be normal, but whose general senses may be dulled:

Q. I see the word insensitive is used not only on the back of the hot pack but also in the instructions, what is Sunbeam's definition of insensitive skin?

A. Insensitive is anything in the way of the heat situation that can't feel heat or respond to that heat. In other words, you wouldn't be able to discern that it is hot or too hot?

Q. Is there any way to quantify that insensitivity other than what you just described what they meant by insensitive skin. In other words, what I am trying to ask is, was there any way to quantify whether someone should use it if they can't feel anything when applied to their skin as opposed to having some sensation or only lack minimal sensation after having some kind of procedure or surgery, what do they mean by that?

In such a case, even common sense would not allow an average consumer to avoid the risk of dangerous burns.

Finally, the record before the Court suggests that Plaintiff, in fact, followed the above directions. She indicated that she read the heating instructions on the gel pack for use in a microwave. (Garrity Dep. 33:2-16.) She then took the Hot Pack and put it in the microwave for only thirty seconds. (Id. at 44:21-25.) Although her microwave was rated as an 800 watt oven, Mr. Schiffman noted that there was no listing of the microwave power anywhere on the oven and "[i]ndicating 700 watts is . . . without merit because . . . most consumers have no idea what the wattage of their ovens are . . . [and] not all 700 watt ovens are alike." (Pl. Mem. Opp. Mot. Summ. J., Ex. F., 5, 25.) When she removed the Hot Pack, the heat indicator read "medium." (Garrity Dep. 45:1-5.) Thereafter, she flattened it out, checked for leaks, placed it in the white sleeve, and put it on her stomach for approximately three minutes. (Id. at 45:6-46:22.) She then wrapped the pack in a kitchen towel to keep it from sliding off, and held it on her abdomen for approximately thirty-five to forty-five minutes. (Id. at 46:15-47:25.) Plaintiff denied that she had

(Prins Dep. 58:16-59:23.)

A. If I can't sense the heat or can't tell how hot it is, then I think that is insensitive. So you have to look at it as a person who can feel some heat, but can't discern it.

Q, Do any the instances of the information that was supplied with this product to the consumer in any way further define insensitive?

A. I don't see it on here other than the word on there. It described the different types of people who shouldn't use it.

Q. Some of the other cautions are people who are diabetic or have poor blood circulation?

A. Yes, and a helpless person.

Q. Who can't take it off themself.

A. Right.

any insensitivity or neuropathy in her abdominal area. (<u>Id.</u> 62:2-65:14, 75:2-14.) Nonetheless, she suffered serious burns on her abdominal area.

Once again, the facts taken in the light most favorable to Plaintiff suggest that an average user, exercising due care and following the instructions, would not be able to easily avoid the dangers involved in the use of the product. Thus, this factor weighs in favor of Plaintiff.

e. The User's Anticipated Awareness of the Dangers Inherent in the Product and Their Avoidability, Because of General Public Knowledge of the Obvious Condition of the Product, or of the Existence of Suitable Warnings or Instruction

Under the sixth Wade factor, the Court must assess the ordinary consumer's anticipated awareness of the dangers allegedly inherent in the product, and the avoidability of such dangers. Bowersfield v. Suzuki Motor Corp., 111 F. Supp. 2d 612, 622 (E.D. Pa. 2000). Defendants contend that "[t]he fact that when you place any item in a microwave and heat it up it can get hot and, thus, can cause a burn, is a basic principle." (Defs.' Mem. Supp. Mot. Summ. J. 24.) What Defendants fail to appreciate, however, is that the Hot Pack was designed to be heated, in accordance with its instructions, to a point that it could be used safely on the body as warm pain relief. Unlike items such as a blowtorch or lighter, a hot pack is not designed to become hot enough to cause serious burns. The gravity of this danger is far from obvious.

Defendants argue alternatively that the Hot Pack had operating instructions in several places warning that "Burns may occur," thereby alerting users to the inherent risk. Defendants' contention, however, omits the context of those warnings. The statement "Burns may occur" does

<sup>&</sup>lt;sup>8</sup> Defendant, citing <u>Dambacher v. Mallis</u>, 485 A.2d 408 (Pa. Super. 1984), analogizes a plaintiff suing a manufacturer of a butcher knife because he cut his finger, on the sole ground that the knife was so sharp that it was likely to cut the human flesh. Unlike a knife, which is designed to be sharp enough to cut, a hot pack is only intended to get hot enough to provide pain relief.

not appear at all under the "Microwave" heating instructions or its related "CAUTION" section on the back of the gel pack. Rather, it appears only under the "CAUTION" section for the "Hot Water" heating instructions and is included as part of another cautionary statement as follows:

Do not use when Heat Guide reads TOO HOT, burns may occur.

Always use cloth cover. Do not apply Hot Pack directly to skin, burns may occur.

(Pl's. Opp. Mot. Summ. J., Ex. B.) The Hot Pack does not warn that when following the microwave heating instructions, obtaining a "Medium" reading on the Heat Guide, and enclosing the gel pack in the cloth cover, a user could still suffer serious burns.

f. The Feasibility, on the Part of the Manufacturer, of Spreading the Loss by Setting the Price of the Product or Carrying Liability Insurance.

The final factor weighs lightly in this Court's analysis. "[A]lthough it is unquestionably true that a manufacturer is almost always able to spread the cost of an injured plaintiff's loss over all users of a product by raising the price thereof, the feasibility of doing so depends upon balancing the remaining factors in the risk/utility analysis." Riley v. Becton Dickinson Vascular Access, Inc., 913 F. Supp. 879, 890 (E.D. Pa. 1995). "In other words . . . when consideration of the preceding six factors leads to the conclusion that the utility of product in question outweighs its risks, such determination compels the further conclusion that shifting the cost of plaintiff's loss to the manufacturer of the product is not fair, and, therefore, not feasible." Id.

In this case, Plaintiff has shown a genuine issue of material fact that the risks involved with normal, intended use of the Hot Pack may outweigh its utility. Assuming this showing to be true, it would be feasible and fair for Defendants to spread Plaintiff's loss by either carrying liability insurance or increasing the price of the product.

# g. <u>Conclusion as to Whether the Product Was Unreasonably</u> <u>Dangerous</u>

Considering the above factors collectively, and viewing the facts and evidence in the light most favorable to the Plaintiff, the Court finds that the Hot Pack is unreasonably dangerous as a matter of law. Clearly, the Hot Pack is socially useful in its ability to provide pain relief. The manner in which the Hot Pack must be heated and used, however, creates significant risks that, while potentially avoidable, are not necessarily obvious to a user exercising due care. According to Plaintiff's experts, such risks could be alleviated with alternative heating instructions and expanded warnings. Defendant has not provided any contrary expert testimony to show that such alterations are economically infeasible or would impair the usefulness of the product. It is now for a jury, and not the Court, to determine whether the product was safe for its intended use and whether Plaintiff can recover on grounds of strict products liability.

#### 2. Whether Plaintiff Can Prove Causation

In an alternative challenge to Plaintiff's strict liability claim, Defendants contend that the alleged defects in the Hot Pack were not the proximate cause of Plaintiff's injuries. "Proximate causation is a necessary element in proving a tort case under theories of strict liability or negligence." Van Buskirk v. Carey Canadian Mines, Ltd., 760 F.2d 481, 492 (3d Cir. 1985). A proximate cause is "a substantial contributing factor in bringing about the harm in question." Id.

Notably, however, causation is not the central focus of Pennsylvania strict products liability law; rather, "the focus is on whether the product was sold in an unreasonably dangerous condition for reasonably foreseeable uses." Parks v. AlliedSignal, Inc., 113 F.3d 1327, 1333 (3d Cir. 1997). Causation need not be proven directly and may be shown by process of elimination or circumstantial evidence. Id. (citing Pennsylvania product liability cases where the appellate courts

have reversed trial courts for not sending to the jury cases in which causation had not been directly demonstrated). "In the products liability area, Pennsylvania has determined that it is economically and socially desirable to hold manufacturers liable for accidents caused by their defective products, without introducing negligence concepts of comparative fault that would weigh the manufacturer's negligent conduct against that of the injured product user. " Id.

To that end, when determining causation in connection with a strict liability claim, the threshold question before the jury is whether the plaintiff's actions were foreseeable. <u>Id.</u> at 1332. "[T]he manufacturer is responsible for making the product safe for all foreseeable uses." <u>Id.</u> "[I]f both a manufacturer's defect and a plaintiff's conduct are found to be proximate causes, the plaintiff will recover unless the defendant meets the burden of proving that plaintiff's conduct was so unforeseeable as to constitute a superseding cause." <u>Id.</u>

Defendants offer three arguments to support their claim that none of the alleged defects identified by Plaintiff could have caused her injuries. First, they assert that had the heat indicator on the Hot Pack not functioned properly, as opined by Schiffman, Plaintiff would have surely noticed that the Hot Pack was too hot either when she picked it up with her hands and placed it in the sleeve, or when she removed the Hot Pack after three minutes, in order to wrap it in a kitchen towel.

This first argument, however, disregards the established principle that causation may be proven by process of elimination or circumstantial evidence. Parks, 113 F.3d at 1332. Plaintiff used a Hot Pack distributed or sold by Defendants. After heating it for only thirty seconds, Plaintiff was able to pick it up and place it on her body without noticing any excessive heat, presumably due to the uneven propensities of the gel observed by Mr. Schiffman. Immediately

after using the Hot Pack for the permissible length of time, she noted third degree burns on her abdomen. While Plaintiff's inability to immediately detect her injury is somewhat inexplicable, and while there is no direct evidence that the defect in the heat indicator resulted in the injury, the connection between her use of the Hot Pack and the burn is sufficient, under established Pennsylvania jurisprudence, to permit the causation question to go to a jury.

Defendants' second argument is equally unavailing. Defendants contend that Mr. Schiffman identified, as a design defect, the rupture and subsequent leakage caused by microwaving the Hot Pack. Plaintiff purportedly checked for leakage immediately after taking it out of the microwave and found nothing. (See Garrity Dep. at 45:9-15.) Moreover, Defendants argue that Plaintiff has produced no evidence that the leaking gel caused her burn, particularly in light of the fact that the dimensions of Plaintiff's burn were nearly identical to the dimensions of the entire hot pack.

Again, Defendants seemingly misunderstand the summary judgment standard of review. Although Plaintiff indicated that she flattened out the gel pack to check for leaks, she also testified that when she removed the pack from the kitchen towel she noticed some of the red gel on that towel. Mr. Schiffman noted that he likewise had problems with gel ruptures. Finally, the fact that Plaintiff's expert testified that the dimensions of Plaintiff's burn were precisely the same as those of the entire hot pack does not negate a finding that the gel may have leaked and caused burns in that area. Any inconsistences in this evidence simply create questions of fact that fall precisely within the province of the jury.

Finally, Defendants argue that Plaintiff did not read all of the warnings already on the Hot Pack, did not heed the direction on the box to read the instructions inside the box, did not follow

the instructions to heat the Hot Pack for sixty seconds in a microwave oven, and applied the Hot Pack to her abdomen, which was purportedly "insensitive."

Whether such alleged missteps by Plaintiff were superseding causes of her injuries, however, is again for the jury. As repeatedly discussed above, Plaintiff has presented evidence that her actions were foreseeable, such that she could survive a motion for summary judgment. As a manufacturer is responsible for making its product safe for all foreseeable uses, the Defendants now have the burden of proving, to a jury, that Plaintiff's conduct was so unforeseeable as to constitute a superseding cause.

In short, the Court finds a genuine issue of material fact as to whether Plaintiff could establish proximate causation. Accordingly, we decline to grant summary judgment in favor of Defendants on this ground.

## B. <u>Negligence and Breach of Warranty Claims</u>

Defendants' final effort to obtain summary judgment on Plaintiff's Complaint alleges that her negligence and breach of warranty claims fail as a matter of law. The Court disagrees.

To sustain a cause of action in negligence, a plaintiff must prove four elements: (1) a duty or obligation to conform to a standard of conduct recognized by law; (2) a breach of that duty by the defendant; (3) a causal connection between the defendant's breach of duty and the resulting injury; and (4) injury or harm suffered by the plaintiff. Spence v. ESAB Group, Inc., Civ. A. No. 07-583, 2008 WL 450436, at \*2 (E.D. Pa. Feb. 15, 2008). Defendant argues that, for the reasons set forth above, Plaintiffs cannot show either that the Hot Pack was defective or that any of the alleged defects were the proximate cause of Plaintiff's injury. As the Court rejected these precise arguments above, we likewise reject them here.

The implied warranty of merchantability and fitness for particular purpose arise by operation of law and were created to protect buyers from products sold below commercial standards or unfit for the buyer's purposes. Altronics of Bethlehem, Inc. v. Repco, Inc., 957 F.2d 1102, 1105 (3d Cir. 1992). In order to meet the definition of "merchantable," products must, inter alia, be "fit for the ordinary purpose for which such goods are used." 13 PA. CONS. STAT. ANN. § 2314(b)(3). As discussed above, Plaintiff has presented sufficient evidence on which a jury could find that the Hot Pack was unfit for the ordinary purpose for which such items are used. Thus, the Court denies Defendants' motion on this claim.

#### IV. CONCLUSION

In ultimately holding that the Hot Pack at issue was "unreasonably dangerous" as a matter of law, the Court does not express any opinion as to whether Plaintiff is entitled to recover under strict liability, tort, or breach of warranty theories for the injuries allegedly caused by that Hot Pack. Rather, balancing the utility of the Hot Pack against both the seriousness and likelihood of injury and the availability of precautions that might prevent injury, the Court recognizes that a jury must now resolve the numerous factual issues inherent in the record of this case.

Accordingly, the Court denies Defendants' Motion for Summary Judgment.

#### IN THE UNITED STATES DISTRICT COURT

#### FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LYNN STREET, :

.

Plaintiff, : CIVIL ACTION

:

v.

.

SUNBEAM PRODUCTS, INC.

CVS PHARMACY, and : NO. 07-2772

CVS/CAREMARK CORPORATION

:

Defendants. :

### **ORDER**

AND NOW, this 13<sup>th</sup> day of *November*, 2008, upon consideration of the Motion by Defendants Sunbeam Products, Inc. ("Sunbeam") and CVS Caremark Corporation ("CVS") for Summary Judgment (Docket No. 20) and the Response thereto of Plaintiff Lynn Street (Docket No. 22), it is hereby **ORDERED** that the Motion is **DENIED**.

BY THE COURT:

s/ Ronald L. Buckwalter

RONALD L. BUCKWALTER, S.J.